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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,270	05/02/2006	James A. Baum	38-21(52806)B	4307

27161 7590 05/27/2009

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,270	BAUM ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/14/08, 5/7/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14,16-22,27,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *16-20 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 14, 21-22, 27 and 35-36* is/are rejected.

7)☒ Claim(s) *6-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group III (SEQ ID NO:5) in the reply filed on 30 March 2008 is acknowledged.

The traversal is on the ground(s) that Applicant has argued this in the PCT phase and it is now the Office's burden to address those arguments. This is not found persuasive. Those arguments are not available to the examiner and are not of record in the instant application; if they are not presented below, they cannot be addressed. Additionally, there is no record of a protest being filed in PCT/US04/21692 within one month of the mailing of the lack of unity (*i.e.*, within one month of 3 June 2005).

The traversal is on the ground(s) that the problem to be solved is the identification of novel insecticidal proteins; the disclosed sequences are novel and non-obvious. This is not found persuasive. The basis for identifying inventions in lack or unity is not the problem to be solved but the technical feature linking the claims. The technical feature linking the groups appears to be tIC insecticidal proteins from Bacillus thuringiensis. WO 01/87940 teaches the tiC insecticidal protein tiC851 and a nucleic acid encoding it (pg 27, line 14, to 28, line 4; pg 65, line 21, to pg 67, line 8). This nucleic acid would hybridize to at least one of SEQ ID NOs:2, 3,5, 7, 9, 11, 12, 15-30 or 32 under "specific hybridization conditions" is defined in the instant specification as conditions that enable identification of distantly related sequences (pg 21, lines 10-15) and under "stringent hybridization conditions", which the specification does not define. Thus, the claimed sequences are anticipated, and the technical feature linking the groups is not special. It is worth noting that the scope of the claims is broader than that of the disclosed sequences.

Applicant urges that under PCT Rule 13.1 a technical feature is one that defines a contribution over the prior art; each of the sequences presented is novel and nonobvious, and none would hybridize to the tIC851 sequence under any conditions in the specification. This is not found persuasive. The claims are not drawn to SEQ ID NO:2 et al; they are drawn to sequences that hybridize to SEQ ID NO:2 et al. As discussed above, "specific hybridization conditions" is defined in the instant specification as conditions that enable identification of distantly related sequences (pg 21, lines 10-15). "Stringent hybridization conditions" are not defined in the specification. The hybridization conditions in the claim are not limited to any disclosed in the specification. As any hybridization condition would be "stringent", the prior art sequence would hybridize to the nucleic acid of SEQ ID NOs:2, 3,5, 7, 9, 11, 12, 15-30 or 32, and thus, claim 1, at least, is not novel.

Applicant urges that tIC is an internal corporate nomenclature, and implies no structural relationship; further the claims no longer recite the limitation "specific hybridization conditions". This is not found persuasive. "Stringent hybridization conditions" are not defined in the specification; thus, any hybridization conditions would be "stringent".

The requirement is still deemed proper and is therefore made FINAL. Claims 16-20 and 28 and nucleic acids encoding SEQ ID NOs:2, 4, 8, 10 and 32 are withdrawn from consideration as being drawn to nonelected inventions.

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

the references have been cited by the examiner on form PTO-892 or by Applicant on form PTO-1449, they have not been considered.

3. The drawings published in parent WO 2005/019414 are missing from this application. Additionally, the sequence identifiers for all the sequences in that figure should be included in either the figure or its brief description.

4. In response to Applicant's response filed 5 February 2009 to the Request for Information mailed 5 August 2008, strain EG2158 was made publicly available by the claims of US Patent 5,024,837.

Claim Objections

5. Claims 2-5, 7-8, 14, 21, 27 and 35 are objected to because of the following informalities:

In claims 2-5 and 8, line 1, a comma is missing before "wherein".

In claims 7, 14 and 21, line 2, a comma is missing before "wherein".

In claim 27, "SEQ ID NO:6" is repeated twice.

In claim 35, there is an improper article before "polynucleotide" in line 1.

6. Claims 1-8, 14, 21-22, 27 and 35-36 are objected to for reciting non-elected sequences.

7. Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The DNA construct of claim 27 already encodes a protein of SEQ ID NO:4, 6, 10 or 33; thus, for these, claim 35 fails to set forth a limitation. SEQ ID NO:8 is not

in claim 27; thus, claim 35 is broader than the parent claim. The claims were not examined for art against SEQ ID NO:4, 8, 10 and 33.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 14 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The full scope of nucleic acids encoding Bacillus thuringiensis toxins are not described

Claims 1-5 are drawn to nucleic acids encoding Bacillus thuringiensis toxins, wherein the nucleic acids hybridize under "stringent" conditions to SEQ ID NO:6.

The specification does not describe structural features that distinguish toxins from *B. thuringiensis* from toxins or other proteins from other sources, including manmade toxins and proteins.

Thus, the specification does not describe nucleic acids within the full scope of the claims.

The full scope of nucleic acids that hybridize to SEQ ID NO:6 and encode insecticidal proteins are not described

Claim 14 is drawn to a method of detecting a nucleic acid sequence encoding an insecticidal protein, wherein the nucleic acids sequence hybridizes to SEQ ID NO:6.

The species described in the specification, SEQ ID NO:3, which has 57.7% identity to SEQ ID NO:5, SEQ ID NO:7, which has 51.6% identity to SEQ ID NO:5, SEQ ID NO:9, which has 47.9% identity to SEQ ID NO:5, SEQ ID NO:32, which has 45.6% identity to SEQ ID NO:5, SEQ ID NO:13, which has 33.2% identity to SEQ ID NO:5, and SEQ ID NO:30, which has 28.6% identity to SEQ ID NO:5, do not describe the full scope of the claimed genus.

As discussed above, the specification does not describe the structural features required for insecticidal toxicity. The specification also does not describe structural features that distinguish insecticidal toxins from proteins that are not insecticidal.

The full scope of nucleic acids encoding toxins with 70% identity to SEQ ID NO:6 or a variant of it are not described

One interpretation of claims 21-22 is that they are drawn to nucleic acids encoding toxins that have 70% identity to SEQ ID NO:6 or a variant thereof.

As discussed above, the specification fails to describe any structural features required for toxicity. Further, neither the specification nor the prior art describe the necessary and sufficient structural elements of a toxin.

Variant proteins are defined in the specification (pg 26, lines 13-40) as follows:

> With reference to the proteins of the instant application, the terms "variant amino acid sequence", or "amino acid sequence variant", or "modified amino acid sequence variant" are intended to refer to amino acid sequences that are substantially equivalent to the amino acid sequences of the present invention ….

> Proteins that are substantially equivalent to the proteins of the instant application are intended to be biologically functionally equivalent. As used herein, the phrase "biological functional equivalents", with respect to the insecticidal proteins of the present invention, are peptides, polypeptides and proteins that contain a sequence or moiety exhibiting sequence similarity to the novel peptides of the present invention ... and that exhibit the same or similar functional properties as that of the polypeptides disclosed herein, including insecticidal activity.

Thus, it appears that any toxin would be a variant of SEQ ID NO:6.

The only species described in the specification are SEQ ID NO:6, 4, 8, 10 and 33; the latter four have 88.3%, 78.2%, 80.3% and 79.2% identity to SEQ ID NO:6, respectively. Thus, the specification does not describe the full scope of toxins, and does not describe the full scope of these claims.

Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO:6, 4, 8, 10 and 33 are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described nucleic acids within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, Applicant does not appear to have been in possession of the claimed genus at the time this application was filed.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 14, 21-22, 27 and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 14 does not set forth any steps involved in the method/process; it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is noted that everything in the claim is preamble.

Claim 21 is indefinite in its recitation of "said toxin protein comprises a sequence that exhibits at least about 70% sequence identity to a nucleotide sequence selected from the group of amino acid sequences consisting of …". A protein cannot have identity to a nucleotide sequence and a nucleotide sequence is not an amino acid sequence. Further, 70% identity to a variant of SEQ ID NO:6 is indefinite as the specification does not define "variant"; thus, the polynucleotide does not have 70% identity to a fixed reference sequence.

Claim 27 is indefinite in its recitation of "at least about 70% identical". There is nothing in the specification to provide any indication as to what range of specific identity is covered by the term "about." Thus, the minimum number implies by "at least" in unclear, and the metes and bounds of the claim are unclear.

In claim 27, it is unclear if a nucleic acid that is 70% identical to SEQ ID NO:13 could encode a SEQ ID NO:6; SEQ ID NO:13 has 33.2% identity to SEQ ID NO:5, which encodes SEQ ID NO:6.

Claim 35 lacks antecedent basis for the limitation "a polynucleotide sequence of claim 27" as claim 27 is drawn to a recombinant DNA construct.

Claim Rejections - 35 USC §§ 102, 103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 5, 14 and 21-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown et al (1994, US Patent 5,308,760).

Brown et al teach isolation of a gene encoding a Lepidopteran toxin column 8, line 25, to column 11, line 11). The sequences taught by Brown et al would hybridize to SEQ ID NO:5 under "stringent hybridization conditions".

Alternately, if the sequences taught by Brown et al do not hybridize to SEQ ID NO:5 under "stringent hybridization conditions", then the proteins taught by Brown et al makes obvious all nucleic acids that encode them, as the protein has a region with a high degree of identity to SEQ ID NO:6:

```
Qy        124 QMG-LKIEA--LNDMDVTNIDYTSKTGDTIYNGISELTNYTGTTQKMKTDSFQRDYTKSE 180
              |:| :::|   ||   |  :|::      ::|  |          |: :| ||    |::
Db         38 QIGNIEVEPGNLNFSVVPELDFS--VSQDLFNNTS--------VQQSQTASFNESRTETT 87

Qy        181 STSVTNGLQLGFKVA------AKGVVALAGADFETSVT--YNLSSTTTETNTISDKFTVP 232
              ||:||:|:: |  |:      || :|        |:|:  || ||||| |||::  :::
Db         88 STAVTHGVKSGVTVSASAKFNAKILVKSIEQTITTTVSTEYNFSSTTTRTNTVTRGWSI- 146
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Qy        233 SQEVTLSPGHKA-----VVKHD------LRKMVYFGTHDLKGDLKVGFNDKEIVQKFIYP 281
              :| | : |  :      : | |      |   ||  |  | |:                |
Db        147 AQPVLVPPHSRVTATLQIYKGDFTVPVLLSLRVYGQTGTLAGN----------------P 190

Qy        282 NYRSIDLSDIRKTMIEIDKWNHVNTIDFYQLVGVKNHIK-----NGDTLYIDTPAEFTFN 336
              :: |:  :    |:               |  :: ||           ||        |
Db        191 SFPSLYAATYENTL----------------LGRIREHIAPPALFRASNAYIS-------N 227

Qy        337 GANPYYRATFT 347
              |    :| | |
Db        228 GVQAIWRGTAT 238
```

Claim Rejections - 35 USC § 103

15. Claims 1-5, 14 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blenk et al (1996, US Patent 5,573,766) in view of Donovan et al (1988, Mol. Gen. Genet. 214:365-372), further in view of Donovan (1991, US Patent 5,024,837).

The claims are drawn to a nucleic acid that hybridizes to SEQ ID NO:6 and encodes a protein that is toxic to western and southern corn rootworm.

Donovan et al teach cloning a gene encoding a Cry endotoxin from strain EG2158 (pg 368, left column, paragraph 1, to pg 369, right column, paragraph 2). Further, they teach that the strain has 5 plasmids, and at least three proteins, at least two of which are encoded by the same plasmid (pg 567, right column). Donovan et al do not teach cloning additional toxins from strain EG2158.

Blenk et al teach that a Bacillus isolate encoding more than one toxin, including one whose activity was not known in the bacteria itself (column 2, lines 24-49). Blenk et al teach the iaolation of the gene encoding endotoxin encode on the extrachromosomal and chromosomal genomes (column 6, line 60, to column 8, line 30).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to cloning additional toxins from the strain EG2158 taught by Donovan et al. One of ordinary skill in the art would have been motivated to do so because Blenk et al teach that Bacillus isolates can encode multiple toxins. In doing so, one would isolate a nucleic acid that hybridize to the instant SEQ ID NO:5 and encodes a protein that is toxin to western and southern corn rootworm, as shown in the instant specification. The protein, the instant SEQ ID NO:4, has 87.1% identity to SEQ ID NO:6.

Donovan teaches strain EG2158 (claims 1-4 and 9-12)

16. Claims 6-8, 27 and 35-36, to the extent they read on a nucleic acid encoding SEQ ID NO:6, are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding SEQ ID NO:6.

17. Claims 6-8 would be allowable if rewritten or amended to delete recitation of non-elected sequences.

18. Claims 27 and 35-36 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action, and to delete recitation of non-elected sequences.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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May 27, 2009

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638